In re: Barry J. Maurer et al.

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In the Claims:

- 1. (Original) A stable aqueous solution consisting essentially of
- (a) a sphingolipid;
- (b) lactic acid; and
- (c) optionally a stabilizing agent;

said solution having a molar ratio of lactic acid to sphingolipid of 1:1 to 10:1.

- 2. (Original) The solution of claim 1, wherein said sphingolipid is selected from the group consisting of sphingosine, dihydrosphingosine, D-threo-dihydrosphingosine, L-threo-dihydrosphingosine or safingol, DL-threo-dihydrosphingosine, lysosphingolipids, combinations thereof and pharmaceutically acceptable salts thereof.
- 3. (Original) The solution of claim 2, wherein said sphingolipid is L-threo-dihydrosphingosine ("safingol").
- 4. (Original) The solution of claim 1, wherein said sphingolipid is included in said solution in an amount of from about 0.1 to about 30 mg/ml.
 - 5. (Original) The solution of claim 1 further including a stabilizing agent.
- 6. (Original) The solution of claim 5, wherein said agent is an alcohol or a polyhydroxy alcohol.
 - 7. (Original) The solution of claim 6, wherein the alcohol is ethanol.
 - 8. (Original) The solution of claim 6, wherein the polyhydroxy alcohol is mannitol.
- 9. (Original) A reconstitutible composition produced by the process of lyophilizing a solution of claim 1.

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10. (Original) A solution comprising safingol stabilized in lactic acid, wherein a molar ratio of lactic acid to L-threo-dihydrosphingosine or safingol is about 3.5:1 to about 4:1, safingol is present in an amount of about 2.5 to about 5.0 mg/ml, the solution further

comprising ethanol in an amount of about 20 mg/ml or mannitol in an amount of about 5

mg/ml.

11. (Original) A reconsitituble composition produced by the process of lyophilizing

a solution of claim 10.

12. (Currently Amended) A method of making a stabilized solution of a

sphingolipid in lactic acid, comprising:

(a) dissolving the sphingolipid in a dilute lactic acid solution, wherein the

sphingolipid is present in an amount of about .1 to about 30 mg/ml of solution;

(b) adding a stabilizing agent to the product resulting from (a); and

(c) optionally lypholizing the product resulting from [(c)] (b).

13. (Original) A method of treating cancer in a subject in need thereof, comprising

administering to the subject a treatment effective amount of a solution of claim 1, wherein

said cancer is selected from the group consisting of leukemia, lymphoma, neuroblastoma,

lung cancer, skin cancer, prostate cancer, colon cancer, breast cancer, ovarian cancer, cervical

cancer, brain cancer, and pancreatic cancer.

14. (Original) The method of claim 13, wherein the sphingolipid is selected from the

group consisting of sphingosine, dihydrosphingosine, D-threo-dihydrosphingosine, L-threo-

dihydrosphingosine, DL-threo-dihydrosphingosine, lysosphingolipids, combinations thereof

and pharmaceutically acceptable salts thereof.

15. (Canceled)

16. (Original) The method of claim 13, wherein the solution is administered orally

or parenterally.

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17. (Original) The method of claim 13, wherein the solution is administered parenterally.

- 18. (Original) The method of claim 13, wherein the solution is administered intravenously.
- 19. (Original) The method of claim 13, wherein the subject is a human or animal subject.
 - 20. (Original) An emulsion formulation consisting essentially of:
 - (a) lactic acid;
- (b) a sphingolipid, wherein the sphingolipid is present in an amount of about .1 to about 30 mg/ml of solution;
 - (c) optionally an isotonic agent; and
 - (d) a phospholipid present in an amount of about 0.2 to about 200 mg/ml of emulsion.
- 21. (Original) The emulsion of claim 20, wherein the sphingolipid is selected from the group consisting of sphingosine, dihydrosphingosine, D-threo-dihydrosphingosine, L-threo-dihydrosphingosine, DL-threo-dihydrosphingosine, lysosphingolipids, combinations thereof and pharmaceutically acceptable salts thereof.
- 22. (Original) The emulsion of claim 21, wherein the sphingolipid is L-threo-dihydrosphingosine or safingol.
 - 23. (Original) The emulsion of claim 20, wherein the aqueous medium is water.
- 24. (Original) The emulsion of claim 20, wherein a molar ratio of lactic acid to sphingolipid is about 1 to about 10:1.
 - 25. (Original) The emulsion of claim 20, wherein the isotonic agent is glucose.

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26. (Original) The emulsion of claim 20, wherein the phospholipid is selected from

the group consisting of phosphatidylcholine, phosphatidylethanolamine, phosphatidylserine,

phosphatidylinositol, phosphatidylglycerol, phosphatidic acid, lysophospholipid, egg

phospholipid, soybean phospholipid and combinations thereof.

27. (Original) The emulsion of claim 20, wherein the mean particle size of the

emulsion is less than about .03 microns.

28. (Original) The emulsion of claim 20, wherein the emulsion has a shelf-life of at

least six months at a temperature from about 2°C to about 8°C.

29. (Original) A method of making an emulsion comprising a sphingolipid

stabilized in an aqueous medium, comprising:

(a) dissolving the sphingolipid in a dilute lactic acid solution, wherein the

sphingolipid is present in an amount of about .1 to about 30 mg/ml of solution;

(b) optionally adding an isotonic agent; and

(c) adding a phospholipid to the product resulting from (a) or (b) to thereby form said

emulsion.

30. (Currently Amended) A method of treating cancer in a subject in need thereof,

comprising administering to the subject a treatment effective amount of an emulsion of claim

20, wherein said cancer is selected from the group consisting of leukemia, lymphoma,

neuroblastoma, lung cancer, skin cancer, prostate cancer, colon cancer, breast cancer, ovarian

cancer, cervical cancer, brain cancer, and pancreatic cancer.

31. (Original) The method of claim 29, wherein the sphingolipid is selected from the

group consisting of sphingosine, dihydrosphingosine, D-threo-dihydrosphingosine, L-threo-

dihydrosphingosine, DL-threo-dihydrosphingosine, lysosphingolipids, combinations thereof

and pharmaceutically acceptable salts thereof.

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32. (Original) The method of claim 29, wherein the phospholipid is selected from

the group consisting of phosphatidylcholine, phosphatidylethanolamine, phosphatidylserine,

phosphatidylinositol, phosphatidylglycerol, phosphatidic acid, lysophospholipid, egg

phospholipid, soybean phospholipid and combinations thereof.

33. (Original) The method of claim 30, wherein the cancer is selected from the

group consisting of leukemia, lymphoma, neuroblastoma, lung cancer, skin cancer, prostate

cancer, colon cancer, breast cancer, ovarian cancer, cervical cancer, brain cancer, and

pancreatic cancer.

34. (Original) The method of claim 30, wherein the emulsion is administered orally

or patenterally.

35. (Original) The method of claim 30, wherein the emulsion is administered

parenterally.

36. (Original) The method of claim 30, wherein the emulsion is administered

intravenously.

37. (Original) The method of claim 30, wherein the subject is a human or animal

subject.